104 CMR 31.00: HUMAN SUBJECT RESEARCH AUTHORIZATION AND MONITORING

Section

31.01: Scope

Scope. 104 CMR 31.00 establishes the approval process and the standards for human subject research when:

(a) a Department employee, in his or her role as an employee, participates as a research investigator or subject;

(b) the recruitment of any subjects for the research is conducted at a facility or program operated or contracted by the Department, or individuals are recruited as subjects for the research because they receive services from the Department;

(c) the research is conducted at a facility or program operated or contracted for by the Department;

(d) the research involves disclosure by the Department of private information or protected health information; or

(e) the terms of another regulation or an agreement or contract with the Department specifically make 104 CMR 31.00 apply.

No research within the scope of 104 CMR 31.00 may be conducted without the prior approval of the Department's Institutional Review Board.

31.02: Definitions

As used in 104 CMR 31.00:

Client of the Department means any person receiving care or treatment through a facility or program operated or contracted for by the Department.

Human Subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interactions include communication or interpersonal contact between an investigator and subject.

Human Subject Research means research involving human subjects or the use of protected health information or identifiable private information.

Informed Consent means a voluntary agreement to participate in research given by a subject, or if the subject is legally incapacitated (*e.g.*, a minor), by the subject's legally authorized representative, following a process that includes a description of the research and the associated risks and benefits. The subject, or legally authorized representative, must be able to exercise free power of choice to participate in research without undue inducement or any element of force, deceit, duress, or other forms or constraint or coercion. The subject or legally authorized representative must have the capacity to understand and weigh the risks and benefits of the proposed research for the research subject.

Institutional Review Board (IRB) means the Department's Institutional Review Board registered with the U.S. Department of Health & Human Services Office for Human Research Protections.

Private Information means individually identifiable information about behavior occurring in a context in which an individual can reasonably expect no observation or recording is taking place, or information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

31.02: continued

Protected Health Information means individually identifiable information relating to the past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for health care provided to an individual.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research includes an experiment that involves a) a drug other than the use of a U.S. Food and Drug Administration (FDA) approved drug in the course of medical practice; b) a medical device being evaluated for safety or effectiveness; or c) an article subject to regulation by the Federal Food, Drug, and Cosmetic Act where the results of the research are intended to be submitted to or held for inspection by the FDA.

31.03: Research Review, Approval, Implementation, Termination, Suspension or Modification

(1) Promote the Mission of the Department. Research within the scope of 104 CMR 31.00 may only be conducted if the Commissioner, or designee, determines that the research will promote the mission of the Department as defined in M.G.L. c.19, §1.

(2) Mandatory Review by the IRB. All research involving human subjects must be reviewed and approved by the IRB prior to implementation. As determined by the IRB, for research to be approved it must meet the requirements and standards set forth in 104 CMR 31.05.

(3) Research Implementation. Department Area Directors, Facility Directors, or Directors of Programs operated by or contracted for by the Department must accept the approval or disapproval of research by the IRB. However, the applicable Area Director(s), Facility Director(s), and Directors of Programs may place restrictions on implementing research at a particular site. The restrictions that are placed must be reasonable and minimized as determined by the IRB.

(4) Power to Terminate, Suspend or Modify. The Commissioner or the IRB may as to any research, including research formerly approved by the IRB, take the following actions for good cause:

(a) terminate the research;
(b) restrict the implementation of the research at a particular Department site;
(c) impose additional conditions;
(d) require additional IRB review;
(e) delay the implementation of the research until the completion of the additional review; or
(f) temporarily suspend the research, pending other action.

(5) Final Decision. Any action pursuant to 104 CMR 31.03 is final and not subject to further review, judicial or otherwise. Written notice of the action taken and the reason for it will be given promptly to the principal investigator.

31.04: Institutional Review Board (IRB)

(1) IRB. The IRB shall be guided by the ethical principles regarding human subject research set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The "Belmont Report").

(2) IRB Operations and Review Process. The IRB shall operate in compliance with and review research in accordance with the requirements and standards set forth in:

(a) 45 CFR Part 46 and 21 CFR Parts 50 and 56;
(b) M.G.L. c. 94C;
(c) applicable state laws relating to the use and disclosure of personal data;
(d) 104 CMR 31.05;

(e) Health Insurance Portability and Accountability Act of 1996 (HIPAA, Pub.L. 104–191, 110 Stat. 1936, enacted August 21, 1996); and 104 CMR 27.17: *Records and Records Privacy* and 28.09: *Records and Records Privacy*;
(f) if the research is supported by a federal department or agency, the additional human subject regulations and policies, if any, imposed by the supporting department or agency; and
(g) applicable procedures and guidelines developed by the IRB.

(3) Membership. The Commissioner shall appoint the members of the IRB as required by the standards set forth in 104 CMR 31.04(2). If the IRB reviews research involving minors, it must have one or more members knowledgeable about and experienced in working with children. A member may be removed at any time at the discretion of the Commissioner.

31.05: Research Standards, Monitoring and Audit

Research at all times must meet the standards and requirements set forth in 104 CMR 31.04(2)(a) through (g). In addition, for research to be approved by the IRB it must meet the following standards:

(1) Informed Consent Process. The participation of each subject in a research project requires the written informed consent of the subject or the subject's legally authorized representative unless specifically waived by the IRB in accordance with the standards set forth in 104 CMR 31.04.
(a) The informed consent process must begin with a description of the research and include an evaluation of the subject's comprehension. The process must also include an on-going assessment of each subject's continued consent to participate in the research.
(b) If research will involve clients of the Department as subjects, the informed consent process must provide the following information:
1. a statement to the effect that the provision of Department services to the client is not dependent on his or her participation in the research; and
2. where applicable, a description of any controlled substance as defined in the Massachusetts Department of Public Health regulations implementing M.G.L. c. 94, and any other substances to be used, and their anticipated effects, side effects and interactions.

(2) Objection by the Subject. An individual's participation in a research project must cease if the individual objects, by verbal or nonverbal means, to participation. This applies even if the individual's legally authorized representative consents to the research.

(3) Monitoring. The IRB shall monitor all approved research at least once a year, or once during the duration of the study, whichever is shorter. The monitoring must be appropriate to the type of research and the degree of risk to subjects. At a minimum the research shall be monitored at last once a year, or once during the duration of the study, whichever is shorter.

(4) Subject to Audit. A person involved in conducting research who receives compensation, either money or in-kind, for the research must provide fiscal records pertaining to the compensation upon request of the IRB.

31.06: Complaints and Sanctions.

(1) Complaints Regarding Human Subject Research. Any person may file a complaint about a human subject research project with the chairperson of the IRB. Such complaints shall be resolved in accordance with the standards set forth in 104 CMR 31.06..

(2) Initial Review. The chairperson, or designee, shall conduct a preliminary investigation. If the chairperson determines the complaint has merit it shall be referred to the IRB for further review. The chairperson has the right to immediately suspend a study that poses an immediate risk to participants. The complaint shall be investigated by the chairperson or referred to the Department's Office of Investigations. If the chairperson determines that the complaint falls within the scope of 104 CMR 32.04(2)(d), it shall be referred to the Office of Investigations and resolved in accordance with 104 CMR 32.00: *Investigation and Reporting Responsibilities*. However, in making the referral, the IRB retains its authority under 104 CMR 31.03(4) to make decisions with respect to research that may relate to the complaint.

31.06: continued

(3) IRB Investigation. The IRB, as part of its investigation of a complaint, shall provide the complainant and the principal investigator the opportunity to present relevant information to the IRB. Within 30 days of receiving the complaint, or as soon thereafter as practical, the IRB shall take such action as it determines appropriate, including, but not limited to:

1. termination of the research;
2. imposition of additional conditions on the research;
3. temporary suspension of the research pending further investigation or other action; or
4. dismissal of the complaint.

(4) Notification. The IRB shall give prompt notification to the complainant and the investigator(s) of its action. The IRB shall keep written records of all complaints, investigations, action taken, and reasons for such action.

(5) No Appeal. Any action taken by the IRB with respect to research is final and not subject to further review, judicial or otherwise.

(6) Department Complaint Process. Nothing in 104 CMR 31.06 shall preclude the chairperson from referring a complaint for investigation under 104 CMR 32.00: *Investigation and Reporting Responsibilities*.

REGULATORY AUTHORITY

104 CMR 31.00: M.G.L. c. 19, §§ 1 and 18; c. 123, § 2.